

Exhibit 405

United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al.
v. Dey, Inc., et al., Civil Action No. 05-11084-PBS

**Exhibit to the August 28, 2009 Declaration of Sarah L. Reid in Support
of Dey's Opposition to Plaintiffs' Motion for Partial Summary Judgment**

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

**In re: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION**

)
) **MDL No. 1456**
) **Master File No. 01-CV-12257-PBS**
) **Subcategory Case No. 06-11337**
) **Hon. Patti B. Saris**

THIS DOCUMENT RELATES TO:

) **Magistrate Judge**
) **Marianne B. Bowler**

*United States of America ex rel. Ven-A-Care of
the Florida Keys, Inc., et al. v. Dey, Inc., et al.,*
Civil Action No. 05-11084-PBS

**DECLARATION OF W. DAVID BRADFORD, PH.D. IN FURTHER
SUPPORT OF
DEY, INC., DEY, L.P., AND DEY L.P., INC.'S
MOTION FOR PARTIAL SUMMARY JUDGMENT AND IN
OPPOSITION TO THE UNITED STATES' CROSS-MOTION FOR
PARTIAL SUMMARY JUDGMENT**

Declaration of Professor W. David Bradford, Ph.D.

- 1) W. David Bradford, declares, pursuant to 28 U.S.C. § 1746, that:
 1. I am presently employed at the University of Georgia, where I am the Busbee Chair of Public Policy and Professor in the Department of Public Administration and Policy. I have over 17 years of research experience in the area of health economics in general, much of which has focused on insurance, and the role of incentives and regulations on economic efficiency in particular. I have been principal investigator on 15 funded grants and projects. Several of these projects have focused on the functioning of various components of Medicaid, and involved working directly with Medicaid agency personnel in another state. As of this writing, I have published 45 articles in peer-reviewed publications, have another 30 reports and other publications, and serve as an Editor of the journal *Health Economics Letters*, and am an Associate Editor of the journal *Health Economics*.
 2. On March 6, 2009, I submitted an Expert Report in this matter. On April 23, 2009, plaintiff experts submitted Rebuttal Reports. Subsequently on May 7, 2009, I submitted a Rebuttal Report. On June 26, 2009, I submitted a Declaration in support of Dey's partial summary judgment motion in this matter.
 3. In connection with preparation of my reports, I have reviewed depositions, documents, and data produced in this litigation, as well as a variety of publicly available information. The materials I considered are listed in Appendix B to my Expert Report. My curriculum vita was attached as Appendix A to my declaration dated June 26, 2009.
 4. I submit this declaration in support of Dey's Motion for Partial Summary Judgment and in Opposition to the United States' Cross-Motion for Partial Summary Judgment in this matter. Based on the work I have performed in preparing my expert reports, I have been asked by counsel for Dey to:
 - a. Examine the claims data produced by the plaintiffs regarding expenditures on at-issue drugs by various state Medicaid agencies and examine the basis of payments used by various state Medicaid agencies for drug payments;
 - b. Examine plaintiff expert Dr. Mark Duggan's declaration dated July 23, 2009, regarding state claims data and methodology used by plaintiff experts in calculating damages where claims data was not produced or used by plaintiff experts;

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- c. Examine the data produced by the plaintiffs regarding pricing used by the Medicare in determining payment levels for at-issue drugs
5. For the purposes of this motion, my declaration focuses on these areas and does not set forth all of the opinions I have rendered in this case.

I. Availability of Medicaid state claims data

- 2) Three sources of Medicaid claims data were produced in this matter. I have discussed these data sources in detail in my expert report and prior declaration.¹ Detailed claims-level data for Dey's drugs was produced directly by 32 state Medicaid agencies. This claims level data is the most complete and detailed data that allows for the determination of the basis of payment for each claim.² Dr. Duggan has analyzed claims data from state Medicaid agencies for only 14 of the 32 states, less than half the total. These 14 states for the entire time period at issue account for 63% to 68% percent of paid amount for the Dey products at issue as Dr. Duggan appears to indicate in his declaration.³ However, state claims data was not produced for all time periods at issue for these 14 states. My review of Table 27 in Dr. Duggan's original report shows that the state claims data Dr. Duggan actually analyzed for these 14 states account for less than 55% of the total paid amount.
- 3) In addition to the detailed state claims data, two other Medicaid utilization datasets were produced in this matter. The first dataset consisted of three components: the State Medicaid Research Files (SMRF), Medicaid Analytic eXtract (MAX), and the Medicaid Statistical Information System (MSIS). The SMRF/MAX/MSIS datasets provide some claims level information. The second dataset, called the State Drug Utilization Data (SDUD), is an aggregate level data that provides no claims level information. These datasets do not include the detailed information needed to accurately determine the basis of payments for each claim.

¹ Expert Report of W. David Bradford at 100, United States ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., No. 05-11084-PBS (D. Mass. Mar. 6, 2009). See also Declaration of W. David Bradford at 10 and 16, United States ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., No. 05-11084-PBS (D. Mass. June 26, 2009).

² In his declaration, Dr. Duggan agrees that state claims data generally provide the most complete detail. See Declaration of Mark G. Duggan at 5, United States ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., No. 05-11084-PBS (D. Mass. July 24, 2009).

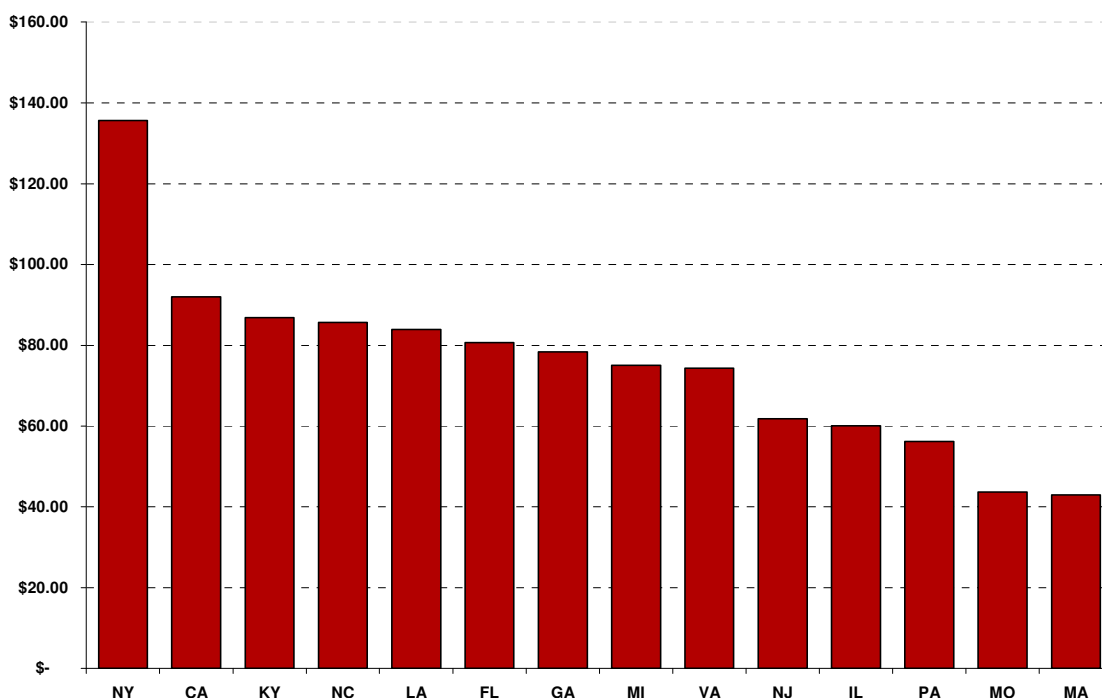
³ Declaration of Mark G. Duggan at 19, United States ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., No. 05-11084-PBS (D. Mass. July 24, 2009).

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II. Across state extrapolation

- 4) In his recent declaration, Dr. Duggan indicates that for the 14 states whose detailed claims data he analyzed, "... the average amounts paid for each NDC ... were very similar".⁴ I examined the average paid amount calculated by Dr. Duggan himself for the 14 states and find that in general average paid amounts across states vary significantly. As shown in Figure 1, the average paid amount for the ipratropium bromide NDC for the highest paying state – New York - is more than 300% greater than Massachusetts.⁵ Ignoring the states with the highest and the lowest paid amount per claim, the difference in average paid amount per claim between California and Missouri is over \$40, a difference of over 100%.

Figure 1: Average paid amount per claim calculated by Dr. Duggan for ipratropium bromide (NDC: 49502068503) in 2001 Q3



Source: Dr. Duggan's work papers

⁴ Declaration of Mark G. Duggan at 20, United States ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., No. 05-11084-PBS (D. Mass. July 24, 2009).

⁵ The ipratropium bromide NDC shown in Figure 1 is the second largest NDC at issue in this matter in terms of the total paid amount.

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- 5) Another revealing comparison shown in Figure 1 is between Kentucky and Pennsylvania, both of which had the same reimbursement benchmark of AWP – 10.00%. Yet the paid amount for Kentucky on average was more than 50% greater than that of Pennsylvania. At various places Dr. Duggan has represented that states have facially same reimbursement methodologies.⁶ Yet, this example shows that even with similar reimbursement methodologies different states end up paying significantly different amounts. I have discussed this state payment variation and the reasons behind it in more detail in my expert report.⁷
- 6) Dr. Duggan also indicates that for the 14 states whose detailed claims data he analyzed, “.... the ratio of damages to total Medicaid spending despite the different adjudication methodologies - is stable”.⁸ In my expert report I identified various other flaws with Dr. Duggan’s damages methodology. Nonetheless, I examined the ratio of damages to total Medicaid spending calculated by Dr. Duggan himself for the 14 states and find that in general these ratios vary significantly across states. As Figure 2 below shows the ratio of damages to total Medicaid spending for the ipratropium bromide NDC for the highest ratio state, New Jersey, is twice as large as the ratio for the lowest ratio state, Missouri. Ignoring the states with the highest and the lowest ratios, the difference between New York and Massachusetts is 34.4%.

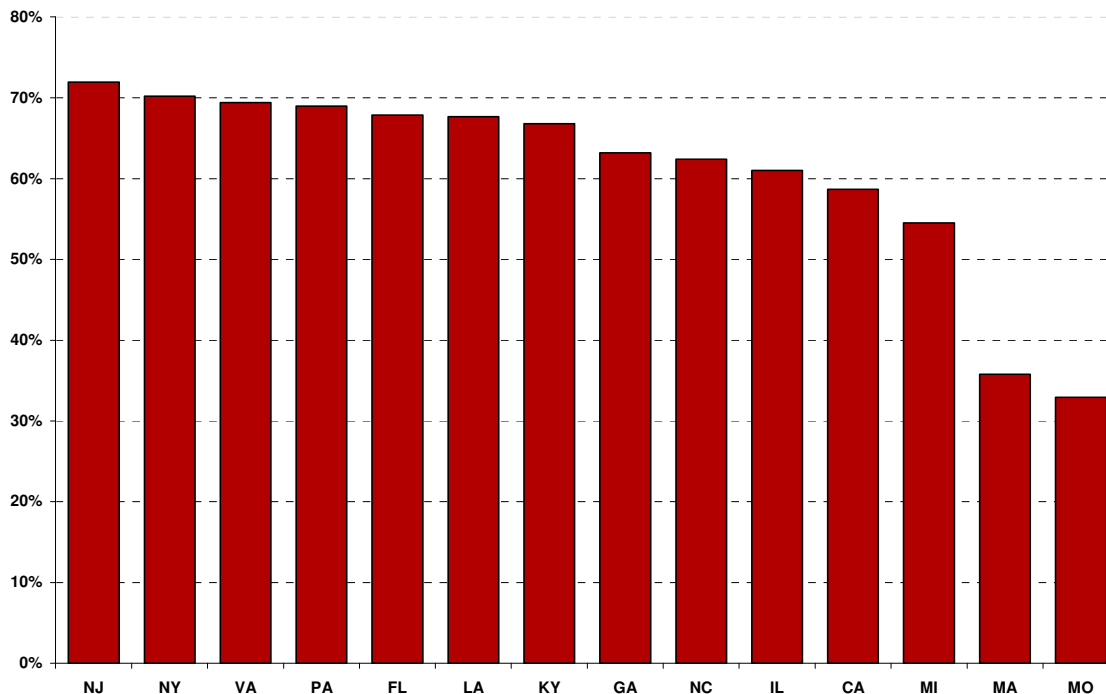
⁶ Declaration of Mark G. Duggan at 24, United States ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., No. 05-11084-PBS (D. Mass. July 24, 2009). See also Expert Report of Mark G. Duggan at 92, United States ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., No. 05-11084-PBS (D. Mass. Jan. 23, 2009).

⁷ Expert Report of W. David Bradford at Section D.4., United States ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., No. 05-11084-PBS (D. Mass. Mar. 6, 2009).

⁸ Declaration of Mark G. Duggan at 24, United States ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., No. 05-11084-PBS (D. Mass. July 23, 2009).

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Figure 2: Average “overcharge” calculated by Dr. Duggan for ipratropium bromide (NDC: 49502068503) in 2001 Q3



Source: Dr. Duggan’s work papers

- 7) Figure 2 above, derived directly from Dr. Duggan’s report, stands in contrast to his declaration that “the ratio of damages to the total amount paid is quite similar across states, whether the state uses the AWP, the WAC, or the DP”.⁹ Dr. Duggan uses this unsupported assertion as a defense of his extrapolation methodology where he applies his average overcharge ratio calculated from 14 states to other states. In my expert report, I showed that if Dr. Duggan had simply applied the methodology he used for 14 states to other 16 states where detailed state claims data were available he would have calculated significantly lower damages. I have reproduced those results in Figure 3 below which illustrate the flaw in Dr. Duggan’s extrapolation methodology.¹⁰ As I discussed in my expert report, there are various other flaws with Dr. Duggan’s damages calculation besides his flawed extrapolation.

⁹ Declaration of Mark G. Duggan at 25, United States ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., No. 05-11084-PBS (D. Mass. July 23, 2009).

¹⁰ Figure 3 here corresponds to Figure 42 from my expert report dated March 6, 2009. The column “Change in differences (\$mm)” shows two decimal places.

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Figure 3: Comparison of Dr. Duggan's results for additional states

State	Dr. Duggan's total Medicaid paid amount (\$mm)	Dr. Duggan's federal differences (\$mm)	Total Medicaid paid amount using claims data (\$mm)	Federal differences using claims data (\$mm)	Change in differences (\$mm)	Change in differences (%)
AK	1.9	0.5	2.1	0.5	-0.02	-4.81
AL	13.1	4.2	12.9	2.5	1.63	39.36
AR	6.6	2.2	6.4	1.8	0.35	16.43
CT	6.5	1.5	6.5	1.6	-0.14	-9.28
DE	2.8	0.6	2.5	0.3	0.25	43.25
HI	1.6	0.4	1.4	0.3	0.07	16.75
ID	3.2	1.0	3.4	1.0	0.00	-0.29
KS	6.3	1.8	5.4	1.4	0.35	19.91
MN	7.9	1.7	7.4	1.6	0.12	7.11
NE	4.6	1.3	4.4	0.9	0.41	32.10
NM	2.5	0.7	2.1	0.5	0.18	25.09
RI	1.5	0.4	1.4	0.2	0.15	38.56
SC	7.5	2.3	6.1	1.9	0.46	19.42
UT	2.1	0.7	1.6	0.5	0.17	24.63
WI	9.6	2.6	8.2	2.0	0.53	20.63
WY	1.2	0.3	1.1	0.3	0.03	8.52
Total	78.9	22.1	73.1	17.5	4.52	20.51

Source: State claims data, and Dr. Duggan's work papers

- 8) As I discussed in detail in my expert report, there is wide variation in paid amount for Dey drugs at issue across state Medicaid agencies.¹¹ Further, as I illustrated above, this fact is directly evident in Dr. Duggan's report as well. The variation in paid amount results from the fact that state Medicaid agencies use a variety of payment bases besides AWP and WAC. These payment bases include the Federal Upper Limit, the state Maximum Allowable Cost, billed charges, and others. I analyzed these payment variations across states in detail in my expert report using the detailed state claims data. SMRF/MAX and SDUD data are not adequate for such payment basis analyses.

¹¹ Expert Report of W. David Bradford at Section D.4., United States ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., No. 05-11084-PBS (D. Mass. Mar. 6, 2009).

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- 9) The paid amount variation directly leads to variation in overcharge ratio as calculated by Dr. Duggan in his report and in contrast to his declaration. Further, it undermines Dr. Duggan's defense for his damages extrapolation across states.
- 10) Summary results of my payment basis analyses were also presented in Figures 5 and 48 of my June 26, 2009 declaration. Percentages shown in Figure 5 were based off of ingredient cost and not the paid amount. Percentages calculated using the paid amount, as reflected in Figure 48, would not match the percentages calculated using ingredient cost shown in Figure 5.

III. Medicare arrays

- 11) As I discussed in more detail in my expert report and my previous declaration dated June 26, 2009, each of the four Durable Medical Equipment Regional Carriers ("DMERCs") determine ingredient payment levels using pricing arrays. Each of the four DMERCs compiles pricing arrays for each drug on a quarterly basis. In his expert report, Dr. Duggan calculated medicare damages using 202 such pricing arrays. Furthermore, Dr. Duggan extrapolates damages over 26 additional missing arrays.
- 12) I have examined the CIGNA pricing arrays for ipratropium bromide for the 18 quarters from 1997 quarter two through 2001 quarter three that were also examined by Carolyn Helton.¹² I found that of the 15 quarters for which I have an AdminaStar array, in eight of these quarters the CIGNA pricing arrays were different than the AdminaStar pricing arrays. Furthermore, a 1% change in Dey's AWP would not result in a different median for these eight AdminaStar pricing arrays.

¹² Declaration of Carolyn Helton, United States ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., No. 05-11084-PBS (D. Mass. July 23, 2009).

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I declare under penalty of perjury that the foregoing is true and correct.

Executed on August 28, 2009.

A handwritten signature in black ink, appearing to read "David Bradford", is written over a horizontal line.

W. David Bradford